

Message

From: Thayer, Kris [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CE4AE3F107749C6815F243260DF98C3-THAYER, KRI]
Sent: 3/30/2021 4:31:31 PM
To: Widener, Kelly [Widener.Kelly@epa.gov]
Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

thanks

From: Widener, Kelly <Widener.Kelly@epa.gov>
Sent: Tuesday, March 30, 2021 12:29 PM
To: Thayer, Kris <thayer.kris@epa.gov>
Subject: Re: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Sure – I'll let them know that you can support but it needs to be next week.
Thanks,
Kelly

From: "Thayer, Kris" <thayer.kris@epa.gov>
Date: Tuesday, March 30, 2021 at 12:03 PM
To: Kelly Widener <Widener.Kelly@epa.gov>
Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Sure but we are swimming in request so I'd prefer not to do it this week.

From: Widener, Kelly <Widener.Kelly@epa.gov>
Sent: Tuesday, March 30, 2021 12:00 PM
To: Thayer, Kris <thayer.kris@epa.gov>
Subject: FW: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information
Importance: High

Kris,

Ex. 5 Deliberative Process (DP)

Kelly

From: Fitzpatrick, Kacey
Sent: Tuesday, March 23, 2021 4:26 PM
To: Widener, Kelly <Widener.Kelly@epa.gov>
Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>
Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Hi Kelly- The chloroprene inquiry is back!!!

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Would Kris or John be interested in doing that?

Kacey Fitzpatrick

Science Communication
Office of Research and Development
U.S. Environmental Protection Agency
Office: 202-564-4086
Cell: Ex. 6 Personal Privacy (PP)

From: Widener, Kelly <Widener.Kelly@epa.gov>

Sent: Monday, March 15, 2021 12:49 PM

To: Fitzpatrick, Kacey <Fitzpatrick.Kacey@epa.gov>

Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>

Subject: Re: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Everyone is good with the edits!

Thanks,
Kelly

From: "Fitzpatrick, Kacey" <Fitzpatrick.Kacey@epa.gov>

Date: Monday, March 15, 2021 at 7:04 AM

To: Kelly Widener <Widener.Kelly@epa.gov>

Cc: "Vasko, Jacqueline" <Vasko.Jacqueline@epa.gov>, Carolyn Hubbard <Hubbard.Carolyn@epa.gov>

Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Hi Kelly- Any update on this? Thanks!

Kacey Fitzpatrick

Science Communication
Office of Research and Development
U.S. Environmental Protection Agency
Office: 202-564-4086
Cell: Ex. 6 Personal Privacy (PP)

From: Fitzpatrick, Kacey

Sent: Friday, March 12, 2021 9:58 AM

To: Widener, Kelly <Widener.Kelly@epa.gov>

Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>

Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

No problem! Okay here is what I have for the response so far. I tried to pull the comments on the Denka response into a shorter bullet list. I highlighted the one I wasn't sure I summarized correctly (but please look at all of them!). I want to make sure all of these comments are appropriate to share too – I don't think we want to get into a back and forth on this. I've attached it as a word doc if that makes it easier to review.

Response to Reporter: Here is a link to the peer review and other related materials:

<https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=349015>

1. Can you tell me what uncertainties were identified in the PBPK model?

Ex. 5 Deliberative Process (DP)

2. Who were the people who did the external peer review?

Ex. 5 Deliberative Process (DP)

3. Was the earlier version of this study something EPA looked at as part of its 2010 decision on cancer risk from chloroprene? Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

- a. Does this revised finding change the agency's view on chloroprene toxicity level? See attached. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

4. How does the agency square the risk estimates for chloroprene and the average to below-average cancer incidence rates found around Denka, per the La. Tumor Registry? Shouldn't the registry's findings suggest the risk is too high or, if not, what other factors countervail against that type of inference?

Ex. 5 Deliberative Process (DP)

Response from Denka that reporter requested EPA to review for accuracy:

DPE identified flaws in the 2010 IRIS study mentioned in your message with EPA back in 2016 and submitted a Request for Correction (RFC) based on those flaws. Despite this not being in agency rules, the EPA representative managing DPE's RFC told the company that its RFC could not identify errors with the study and request the agency to address them, but rather the RFC had to actually contain new information for EPA to consider it. After he told DPE that, the company put in a Request for Reconsideration (RFR) on the denied RFC while it worked simultaneously to generate this new information in the form of a major update to an existing PBPK model.

Note that the 2010 IRIS study actually states that their assessment of health risk would be more accurate using a PBPK model. EPA had already identified questions/work to be done on a PBPK model that was partially produced as long ago as 2004, so DPE contracted scientists with Ramboll to update it based on EPA's previous critiques. Ramboll completed the model, which includes hundreds of parameters to facilitate a more complete understanding of metabolism of the chemical, and DPE submitted it to EPA for review. EPA reviewed it internally, then oversaw an external peer review of the model all while DPE had its RFR filed with the agency.

The peer review panel was composed of a group of scientists from various research backgrounds. The panel was charged with reviewing the scientific process of the model and raising questions for clarification. It provided questions to Ramboll (noted as "uncertainties" in the email below) and the group then worked with EPA's scientists to develop answers to those questions and provide additional clarification. DPE and Ramboll are working to complete that process and will discuss the results with EPA to ensure that the agency's standards are met prior to submitting a new RFC.

As a result of all these changes, EPA indicated it would be more appropriate to submit the model as a new RFC rather than part of the existing RFR. Following agency suggestion, DPE withdrew its RFR and is preparing to submit a new RFC (as described in our release) with the reviewed and revised model as new information. EPA is aware of DPE's intention and expecting the RFC. DPE hopes to have the new RFC submitted by the end of April.

Accuracy of Denka Response:

Ex. 5 Deliberative Process (DP)

From: Widener, Kelly <Widener.Kelly@epa.gov>
Sent: Friday, March 12, 2021 8:24 AM
To: Fitzpatrick, Kacey <Fitzpatrick.Kacey@epa.gov>
Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>
Subject: Re: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Kacey,
Thank you so much for calling her yesterday. I had promised to take my daughter to her appointment so I had to log so
THANK YOU!
Kelly

From: "Fitzpatrick, Kacey" <Fitzpatrick.Kacey@epa.gov>
Date: Friday, March 12, 2021 at 7:23 AM
To: Kelly Widener <Widener.Kelly@epa.gov>
Cc: "Vasko, Jacqueline" <Vasko.Jacqueline@epa.gov>, Carolyn Hubbard <Hubbard.Carolyn@epa.gov>
Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Additional changes from Kris. I think we should develop maybe one statement about the Denka background info instead of doing a line by line review. I can work on that and share later this morning.

1. Can you tell me what uncertainties were identified in the PBPK model?

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

2. Who were the people who did the external peer review?

Ex. 5 Deliberative Process (DP)

3. Was the earlier version of this study something EPA looked at as part of its 2010 decision on cancer risk from chloroprene?

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

a. Does this revised finding change the agency's view on chloroprene toxicity level? See attached.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

4. How does the agency square the risk estimates for chloroprene and the average to below-average cancer incidence rates found around Denka, per the La. Tumor Registry? Shouldn't the registry's findings suggest the risk is too high or, if not, what other factors countervail against that type of inference?

Ex. 5 Deliberative Process (DP)

Finally – the reporter also shared a note he received from Denka and would like it know if it is accurate:

From Denka: Below is some additional background that we hope can clarify the status of the model and the nature of the process DPE has been working through with the agency to date.

DPE identified flaws in the 2010 IRIS study mentioned in your message with EPA back in 2016 and submitted a Request for Correction (RFC) based on those flaws.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) Despite this not being in agency rules, the EPA representative managing DPE's RFC told the company that its RFC could not identify errors with the study and request the agency to address them, but rather the RFC had to actually contain new information for EPA to consider it. After he told DPE that, the company put in a Request for Reconsideration (RFR) on the denied RFC while it worked simultaneously to generate this new information in the form of a major update to an existing PBPK model.

Note that the 2010 IRIS study actually states that their assessment of health risk would be more accurate using a PBPK model.

Ex. 5 Deliberative Process (DP)

EPA had already identified questions/work to be done on a PBPK model that was partially produced as long ago as 2004, so DPE contracted scientists with Ramboll to update it based on EPA's previous critiques. Ramboll completed the model, which includes hundreds of parameters to facilitate a more complete understanding of metabolism of the chemical, and DPE submitted it to EPA for review. EPA reviewed it internally, then oversaw an external peer review of the model all while DPE had its RFR filed with the agency.

The peer review panel was composed of a group of scientists from various research backgrounds. The panel was charged with reviewing the scientific process of the model and raising questions for clarification. It provided questions to Ramboll (noted as "uncertainties" in the email below) and the group then worked with EPA's scientists to develop

answers to those questions and provide additional clarification. DPE and Ramboll are working to complete that process and will discuss the results with EPA to ensure that the agency's standards are met prior to submitting a new RFC.

As a result of all these changes, EPA indicated it would be more appropriate to submit the model as a new RFC rather than part of the existing RFR. Following agency suggestion, DPE withdrew its RFR and is preparing to submit a new RFC (as described in our release) with the reviewed and revised model as new information. EPA is aware of DPE's intention and expecting the RFC. DPE hopes to have the new RFC submitted by the end of April.

Ex. 5 Deliberative Process (DP)

Kacey Fitzpatrick

Science Communication

Office of Research and Development

U.S. Environmental Protection Agency

Office: 202-564-4086

Cell: Ex. 6 Personal Privacy (PP)

From: Widener, Kelly <Widener.Kelly@epa.gov>

Sent: Thursday, March 11, 2021 4:20 PM

To: Fitzpatrick, Kacey <Fitzpatrick.Kacey@epa.gov>

Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>

Subject: FW: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Sorry Kacey!

I've been in never ending meetings today – I got this back from John. Looks like he also asked Kris to review and she hasn't so I will ping her.

Kelly

Kelly Widener
Communications Director
Center for Public Health and Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
Work: (202) 564-6737
Mobile: Ex. 6 Personal Privacy (PP)

From: Vandenberg, John <Vandenberg.John@epa.gov>
Sent: Thursday, March 11, 2021 1:58 PM
To: Widener, Kelly <Widener.Kelly@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: RE: This has info needed I think -- RE: Media request - Denka Performance Elastomer News Release & Background Information

Kelly and Kris - see below. The Yellow highlights are mine (John). [[[Will it ever end (yes, soon for me!))]]

There is a link via the IRIS program to the peer review materials, and other materials related to the Response to comments that can be provided to the reporter:
<https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=349015>

Copying Kris as it would be good for her to review the responses below, especially #4

Ex. 5 Deliberative Process (DP)

From: Widener, Kelly <Widener.Kelly@epa.gov>
Sent: Thursday, March 11, 2021 10:54 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>
Subject: FW: This has info needed I think -- RE: Media request - Denka Performance Elastomer News Release & Background Information
Importance: High

Sorry John,
Some additional questions from the media and JOZ. Please see below. Can you assist?
Thanks,
Kelly

Kelly Widener
Communications Director
Center for Public Health and Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
Work: (202) 564-6737
Mobile: Ex. 6 Personal Privacy (PP)

From: Fitzpatrick, Kacey <Fitzpatrick.Kacey@epa.gov>
Sent: Thursday, March 11, 2021 10:35 AM

To: Widener, Kelly <Widener.Kelly@epa.gov>

Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>

Subject: RE: This has info needed I think -- RE: Media request - Denka Performance Elastomer News Release & Background Information

Hi Kelly, More follow up questions on this! I've filled in the ones you have already answered. Jennifer also asked if the peer review is posted online, and if so, can we add a link to it?

1. Can you tell me what uncertainties were identified in the PBPK model?

Ex. 5 Deliberative Process (DP)

2. Who were the people who did the external peer review?

Ex. 5 Deliberative Process (DP) to

3. Was the earlier version of this study something EPA looked at as part of its 2010 decision on cancer risk from chloroprene? Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

a. Does this revised finding change the agency's view on chloroprene toxicity level? See attached. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

4. How does the agency square the risk estimates for chloroprene and the average to below-average cancer incidence rates found around Denka, per the La. Tumor Registry? Shouldn't the registry's findings suggest the risk is too high or, if not, what other factors countervail against that type of inference? Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Finally – the reporter also shared a note he received from Denka and would like it know if it is accurate:

Also I got this clarification from Denka today. Does it seem accurate?

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Kacey Fitzpatrick

Science Communication

Office of Research and Development

U.S. Environmental Protection Agency

Office: 202-564-4086

Cell: Ex. 6 Personal Privacy (PP)

From: Widener, Kelly <Widener.Kelly@epa.gov>

Sent: Wednesday, March 10, 2021 2:18 PM

To: Fitzpatrick, Kacey <Fitzpatrick.Kacey@epa.gov>

Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>

Subject: Re: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Yep, that works!

Kelly

From: "Fitzpatrick, Kacey" <Fitzpatrick.Kacey@epa.gov>

Date: Wednesday, March 10, 2021 at 2:17 PM

To: Kelly Widener <Widener.Kelly@epa.gov>

Cc: "Vasko, Jacqueline" <Vasko.Jacqueline@epa.gov>, Carolyn Hubbard <Hubbard.Carolyn@epa.gov>

Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

That sounds great! And are we okay to use this response for the other question:

Ex. 5 Deliberative Process (DP)

Kacey Fitzpatrick

Science Communication

Office of Research and Development

U.S. Environmental Protection Agency

Office: 202-564-4086

Cell: Ex. 6 Personal Privacy (PP)

From: Widener, Kelly <Widener.Kelly@epa.gov>

Sent: Wednesday, March 10, 2021 2:09 PM

To: Fitzpatrick, Kacey <Fitzpatrick.Kacey@epa.gov>

Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>

Subject: Re: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Ex. 5 Deliberative Process (DP)

Kelly

From: "Fitzpatrick, Kacey" <Fitzpatrick.Kacey@epa.gov>

Date: Wednesday, March 10, 2021 at 1:23 PM

To: Kelly Widener <Widener.Kelly@epa.gov>

Cc: "Vasko, Jacqueline" <Vasko.Jacqueline@epa.gov>, Carolyn Hubbard <Hubbard.Carolyn@epa.gov>

Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Thanks Kelly! I think instead of mentioning the names of the reviewers, we could instead offer a statement like this:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Also- there was another question. I think the report you send could answer this a bit, but it kind of all goes above my head so I could use help drafting a response 😊

Can you tell me what uncertainties were identified in the PBPK model?

Kacey Fitzpatrick

Science Communication

Office of Research and Development

U.S. Environmental Protection Agency

Office: 202-564-4086

Cell: Ex. 6 Personal Privacy (PP)

From: Widener, Kelly <Widener.Kelly@epa.gov>

Sent: Wednesday, March 10, 2021 1:04 PM

To: Fitzpatrick, Kacey <Fitzpatrick.Kacey@epa.gov>

Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>

Subject: FW: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Here you go:

Peer Reviewers:

Leslie Z. Benet, Ph.D.

Jeffrey J. Heys, Ph.D., P.E.

Jochem Louisse, Ph.D.

Annie Lumen, Ph.D.

Kenneth M. Portier, Ph.D.

Kan Shao, Ph.D.

Jordan Ned Smith, Ph.D.

Raymond S. H. Yang, Ph.D.

Yiliang Zhu, Ph.D.

Thanks,

Kelly

From: "Vandenberg, John" <Vandenberg.John@epa.gov>

Date: Wednesday, March 10, 2021 at 12:57 PM

To: Kelly Widener <Widener.Kelly@epa.gov>, "Dutton, Steven" <Dutton.Steven@epa.gov>

Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

See cover (description of each person follows) Ex. 5 Deliberative Process (DP)

From: Widener, Kelly <Widener.Kelly@epa.gov>
Sent: Wednesday, March 10, 2021 12:37 PM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>
Subject: FW: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information
Importance: High

Hi John, Please see the follow up question below. who were the people who did the external peer review?
Thanks,
Kelly

From: "Fitzpatrick, Kacey" <Fitzpatrick.Kacey@epa.gov>
Date: Wednesday, March 10, 2021 at 12:09 PM
To: Kelly Widener <Widener.Kelly@epa.gov>
Cc: "Vasko, Jacqueline" <Vasko.Jacqueline@epa.gov>, Carolyn Hubbard <Hubbard.Carolyn@epa.gov>
Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Hi Kelly- here was a follow up question: who were the people who did the external peer review?

Kacey Fitzpatrick
Science Communication
Office of Research and Development
U.S. Environmental Protection Agency
Office: 202-564-4086
Cell: Ex. 6 Personal Privacy (PP)

From: Widener, Kelly <Widener.Kelly@epa.gov>
Sent: Tuesday, March 09, 2021 12:26 PM
To: Fitzpatrick, Kacey <Fitzpatrick.Kacey@epa.gov>
Cc: Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>
Subject: FW: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Here you go – some edits below.
Thanks,
Kelly

Denka withdrew the Request for Reconsideration on March 1. Edits here:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: "Fitzpatrick, Kacey" <Fitzpatrick.Kacey@epa.gov>

Date: Tuesday, March 9, 2021 at 11:19 AM

To: Kelly Widener <Widener.Kelly@epa.gov>, "Vasko, Jacqueline" <Vasko.Jacqueline@epa.gov>

Cc: Carolyn Hubbard <Hubbard.Carolyn@epa.gov>

Subject: RE: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Hi Kelly- does this work? I saw EPA is going to formally respond this year- not sure how much we want to say about that. But the request is still open, right?

Ex. 5 Deliberative Process (DP)

Kacey Fitzpatrick

Science Communication

Office of Research and Development

U.S. Environmental Protection Agency

Office: 202-564-4086

Cell: Ex. 6 Personal Privacy (PP)

From: Widener, Kelly <Widener.Kelly@epa.gov>

Sent: Tuesday, March 09, 2021 9:20 AM

To: Fitzpatrick, Kacey <Fitzpatrick.Kacey@epa.gov>; Vasko, Jacqueline <Vasko.Jacqueline@epa.gov>

Cc: Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>

Subject: FW: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

Please see the info provided by John, since they are not very clear on their query, will this work for an overview response?

Thanks,
Kelly

From: "Vandenberg, John" <Vandenberg.John@epa.gov>
Date: Tuesday, March 9, 2021 at 8:49 AM
To: Kelly Widener <Widener.Kelly@epa.gov>, "Dutton, Steven" <Dutton.Steven@epa.gov>
Cc: "Holt, Kay" <Holt.Kay@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>, "Jones, Marjorie" <Jones.Marjorie@epa.gov>
Subject: This has info needed I think - - RE: Media request - Denka Performance Elastomer News Release & Background Information

This might be all that is needed. The only update to this would be that on March 1 Denka withdrew the Request for Reconsideration. They can certainly submit a new Request for Correction, which seems to be their intent, and then the RFC process begins anew. And, therefore the last part about "Next Steps" is that with RFR withdrawal the RFR process is done and no Executive panel review will occur.

Please let me know if this is enough for the response.

John

From: Widener, Kelly <Widener.Kelly@epa.gov>
Sent: Tuesday, March 09, 2021 7:39 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>
Cc: Holt, Kay <Holt.Kay@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: Re: Media request - Denka Performance Elastomer News Release & Background Information

John,
I'm checking on your clarifying question now. Also, we heard back and the deadline is 1pm today.
Kelly

From: "Vandenberg, John" <Vandenberg.John@epa.gov>
Date: Tuesday, March 9, 2021 at 7:28 AM
To: Kelly Widener <Widener.Kelly@epa.gov>, "Dutton, Steven" <Dutton.Steven@epa.gov>
Cc: "Holt, Kay" <Holt.Kay@epa.gov>, "Thayer, Kris" <thayer.kris@epa.gov>
Subject: RE: Media request - Denka Performance Elastomer News Release & Background Information

Hi Kelly,
Sure thing.
It looks like the request for background on the RfC/RfR process, or is it about the Denka bullets at the bottom? I suspect it is both.
Please provide a deadline.
John

From: Widener, Kelly <Widener.Kelly@epa.gov>
Sent: Monday, March 08, 2021 5:05 PM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>
Cc: Holt, Kay <Holt.Kay@epa.gov>
Subject: FW: Media request - Denka Performance Elastomer News Release & Background Information

John,

Can you please assist with a proposed response to this media query? I've asked what the deadline is, I'll let you know as soon as I hear back.

Thanks,
Kelly

From: "Vasko, Jacqueline" <Vasko.Jacqueline@epa.gov>
Date: Monday, March 8, 2021 at 5:02 PM
To: Kelly Widener <Widener.Kelly@epa.gov>
Cc: "Jones, Marjorie" <Jones.Marjorie@epa.gov>, "Fitzpatrick, Kacey" <Fitzpatrick.Kacey@epa.gov>
Subject: Media request - Denka Performance Elastomer News Release & Background Information

Hi Kelly – See below a request for information on Denka's risk model for chloroprene and their recent request for correction to the Agency. It looks like this is CPHEA- Vandenberg, is there anyone that could provide background on this process?

Thank you,

Jacqueline Vasko
Science Communication
Office of Research and Development
U.S. Environmental Protection Agency
Office: (202) 564-9954
Mobile: Ex. 6 Personal Privacy (PP)

From: Mitchell, David <dmitchell@theadvocate.com>
Sent: Monday, March 8, 2021 2:55 PM
To: R6Press <R6Press@epa.gov>; Durant, Jennah <Durant.Jennah@epa.gov>; Hubbard, Joseph <Hubbard.Joseph@epa.gov>; Harwood, Jackie <Harwood.Jackie@epa.gov>
Subject: FW: Denka Performance Elastomer News Release & Background Information

Can any of you shed light on this process?

Denka says they previously filed for a request for reconsideration and withdrew it and now have filed a request for correction.

They also say that EPA had peer-reviewed this new Denka risk model for chloroprene, "which suggests the agency's previous assessment could overstate cancer risk from chloroprene exposure by as much as 130 times."

Help me understand this process, both generally and in reference to chloroprene.

Also you still haven't responded to me regarding my questions about the recent La. Tumor Registry report in connection with Denka and chloroprene.

THE ADVOCATE

BATON ROUGE · NEW ORLEANS · ACADIANA

David J. Mitchell

ED_006848_00002516-00015

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10705 Rieger Road, Baton Rouge, LA 70809

From: Jim Harris <jharris@hdaissues.com>
Sent: Monday, March 8, 2021 1:29 PM
To: Schleifstein, Mark <mschleifstein@theadvocate.com>
Cc: David Laplante <dlaplante@hdaissues.com>
Subject: Denka Performance Elastomer News Release & Background Information

Mark,

Please find **attached** a news release from Denka Performance Elastomer. You may quote me as spokesperson if you decide to use this information. Below are some basic points on what it's about. I hope you received the background information on DPE that I sent you a week or so go. I hope everything is going well.

Best,
Jim Harris
On behalf of Denka Performance Elastomer

Background

- DPE is submitting a formal Request for Correction to the U.S. EPA that includes a new scientific model of chloroprene metabolism as part of the company's continued work with the agency to improve its understanding of chloroprene. A response or action on the request from EPA could take months.
- The model has been reviewed by the agency, undergone external peer review as part of being published in a prestigious scientific journal last year, a testament to the scientific community's confidence in its methods.
- The new model shows previous suggestions by the EPA's Integrated Risk Information System about chloroprene greatly overestimated potential risks to more than 130 times higher than reality.
- DPE's new request to EPA will take the place of a Request for Reconsideration, which the company withdrew as part of EPA's standard process for reviewing agency actions. EPA has suggested that this is a more appropriate process for incorporating the new model into EPA's risk assessment. A final decision and action by EPA on DPE's request could take several months. DPE will continue to work with EPA throughout this process.
- As you know, while DPE has been working with EPA throughout the scientific review process, the company spent over

\$35 million on emissions reduction projects, installing new equipment and improvements to reduce its environmental footprint. This investment has resulted in a similar decrease in concentrations of chloroprene measured in the air near the facility.

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